K092310

SECTION 7 – 510(K) SUMMARY

AUG 2 7 2009

Applicant Information

Submitter's Name and Address:

St. Jude Medical
177 County Road B, East
St. Paul, MN 55117

Contact Name

Thomas Rademacher
Regulatory Affairs Specialist
St. Jude Medical
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Submission Prepared

July 24, 2009

Device Information

Proprietary Name:

SJM Seguin Annuloplasty Ring

Common or Usual Name:

Semi-rigid annuloplasty ring
Mitral repair ring

Classification:

Class II per 21 CFR 870.3800,
Annuloplasty rings

Predicate Device:

SJM Seguin Ring model SARP-(size)

510(k) No. K014037 – cleared January 4, 2002

Device Description:

The SJM Seguin Ring is a semi-rigid ring fabricated from an ultra-high molecular weight polyethylene core surrounded by a polyester sewing cuff, which provides a means for attaching the ring to the mitral annulus as well as a suitable surface for tissue ingrowth.

Intended Use:

The SJM™ Seguin annuloplasty ring is intended to be used for repair of diseased or damaged mitral heart valves that are determined by the physician to be repairable and do not require replacement.

Comparison of Required Technological Characteristics

SJM considers the SJM Seguin Annuloplasty ring to be substantially equivalent in technological characteristics (e.g. design and materials) and intended use to the predicate device. The table below is a comparison of the equivalency characteristics between the SJM Seguin Annuloplasty Ring and the predicate device.

Item	Equivalency
Principles of Operation	Identical
Product Labeling	Substantially Equivalent
Indications for Use	Identical
Physical Characteristics	Substantially Equivalent
Anatomical Sites	Identical
Target Population	Identical
Performance Testing	Substantially Equivalent
Safety Characteristics	Substantially Equivalent
Packaging	Identical
Sterilization	Identical
Shelf-Life	Identical

Summary of Non-Clinical Tests

The following performance characteristics were evaluated:

- Ring Tensile Strength
- Ring Compression Strength
- Suture Pullout Test
- MR Safety Evaluation
- Manufacturing Process validation
- Biological Evaluation
- Sterilization Parameter Evaluation

Conclusion

St. Jude Medical has demonstrated that the SJM Seguin Annuloplasty ring is safe and effective for the intended use. The Seguin Ring is, with respect to intended use and technological characteristics, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

St. Jude Medical
c/o Mr. Thomas Rademacher
Regulatory Affairs Specialist
177 County Road B, East
St. Paul, MN 55117

AUG 2 7 2009

Re: K092310
Seguin Annuloplasty Ring Model SARP-(size), Sizes 24 mm-40 mm (even sizes)
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty ring
Regulatory Class: Class II (two)
Product Code: KRH
Dated: July 24, 2009
Received: July 29, 2009

Dear Mr. Rademacher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Vorhees

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

Indications for Use

510(k) Number (if known): K092310
Device Name: SJM Seguin Annuloplasty Ring
Indications For Use:

The SJM™ Seguin annuloplasty ring is indicated for use in the repair of mitral valves that are diseased or damaged due to acquired or congenital processes.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092310